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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,579	01/25/2001	Hector F. DeLuca	960296.95700	4517

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Jean C. Baker
Quarles and Brady LLP
411 East Wisconsin Avenue
Milwaukee, WI 53202

EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/769,579	DELUCA ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5, 11-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 5, 2005 has been entered.

Claims 1-5, 11-15 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5, 1 1-15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Mathieu et al US Patent 5,665,387.

Mathieu teaches methods of treating autoimmune diabetes which is caused by autoimmune destruction of B cells comprising administering tablets of 1a, 25-dihydroxyvitamin Da (1,25 (OH)2Da) to a subject within at similar doses as instantly claimed. (see col 2, lines 1-10., col 10, lines 1-41', claim 4, 12-17). Autoimmune destruction of B cells leads to Type I diabetes. As described in the Office Action filed on September 9, 2004, at col 4, line 45 Mathieus states that his formulations are prepared for oral administration. Mathieu then claims methods of administering his composition in

tablet or capsule forms (see claims 1-9). Thus, Mathieu has effectively claimed oral administration of his formulations.

Mathieu also discloses modulating the immune system in patients in need of such therapy who have predisposition to develop autoimmune diabetes (abstract, col 2, lines 40-50, 7-8). Such groups of people are construed as predisposed subjects to type I diabetes. (see col 2, lines 45-50). Accordingly, Mathieu describes all elements steps of claims 1-5. Since Mathieu modulates development of diabetes I in subjects, the type I diabetes are viewed to be inherently detectable in such patients with autoantibodies to glutamic acid decarboxylase, because such detectability is a function of the disease. Therefore, Mathieu also meets the limitations of claims 11-15.

Response to Arguments

Applicant's arguments filed December 5, 2005 have been fully considered but they are not persuasive

2. Applicant argues that Mathieus' patent is not enabling for the purposes of "reducing the risk of Type I diabetes in a predisposed human patient by up to 90%." (see Arguments at page 7, 3rd para.). Applicant has offered a Declaration of Inventor Julia Zella, filed on February 14, 2005, to demonstrate that Mathieus' disclosure was inoperative in treating diabetes. (Id.)

First, as has been argued on record previously, applicant appears to argue that the intended use of the method claims is not enabled in Mathieu. However, in a claim drawn to a process, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967)

and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Mathieu teaches the exact same process steps. Thus, the instantly recited clinical outcome is inherent to the methods described in Mathieu.

Under the principles of inherency, if the prior art necessarily functions in accordance with or includes the claimed limitations, it anticipates it. There is no patentably distinct manipulative step between the methods of Mathieu and those of the instant claims. Accordingly, Examiner maintains the rejection.

3. Further, the submitted Declaration does not effectively show that Mathieu is not enabling or is inoperative for anticipation purposes. Examiner has taken the position that prior art reference must be considered together with the knowledge of one of ordinary skill in the pertinent art. In re Samour, 571, F.2d 559, 562, 197 USPQ 1, 3-4 (CCPQ 1978). Applicant Applicant fails to recognize that a prior art reference must be "considered together with the knowledge of one of ordinary skill in the pertinent art." In re Paulsen, 30 F.3d 1475 (Fed Cir 1994). A reference need not, however, explain every detail since it is speaking to those of skilled in the art. Accordingly, even though Mathieu teachings might have been well advanced at the time of its filing for its generic claims, there is simply no evidence showing that Mathieu was insufficiently enabled for the purposes of preparing a reducing the risk of type I diabetes by oral administration of Vitamin D analogs.

4. Moreover, here, the level of skill in the art is advanced and directed to clinical practitioners who understand the steps described in Mathieu. One of ordinary skill in the

art viewing Mathieu's method steps would have been able to exercise oral administration of Vitamin D analogs to treat diabetes.

For example, It was well described at the time of Mathieu's patent that autoimmune destruction of β cells leads to Type I diabetes. (see col 1, lines 1-50). Mathieu teaches methods of treating autoimmune diabetes type I, which is caused by autoimmune destruction of β cells comprising administering tablets of 1a, 25-dihydroxyvitamin D (1,25 (OH)2Dz) to a subject within at similar doses as instantly claimed. (see abstract, claims 4, 10-17). Mathieu also teaches that his compositions can be orally for treating diabetes. (see col 4, line 45-55). Therefore, one of ordinary skill in the art practicing Matheiu would have understood to administer the formulations of Matheiu orally and practice the entire scope of claimed method of Matheiu. Accordingly, the clinical end point would have ultimately and inherently been achieved.

5. Moreover, Applicant's Declaration relies on different vehicle systems. Mathieu's disclosure and patented claims are not limited to only arachis oil, rather an oral composition containing vitamin D. Further, Examiner has noted that aside from the explicit recitation of the claimed intended purpose, the instant application discloses and claims no more than what is disclosed in the Mathieu's method steps. Accordingly, since the disclosure of the instant application fails to explicitly provide any additional detailed information concerning the claimed invention, Examiner has assumed that anyone desiring to carry out such method claims would have known what the final clinical outcome would have been.

6. Finally, Examiner states that "Once the patent has been granted, the Patent and Trademark Office can take no action concerning it, except as provided in 35 USC 135 and 35 USC 251 through 256 and 35 USC 302 through 307." (see MPEP 1305). Accordingly, Examiner has no jurisdiction to entertain Applicant's arguments that Mathieu is a nonenabling disclosure.

Considering the above reasoning, Examiner maintains the rejection.

Conclusion

7. **No claims are allowed.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER